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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,109	07/01/2003	Richard C. Ewers	USGINZ02110	3376
40518 7590 05/16/2008 LEVINE BAGADE HAN LLP 2483 EAST BAYSHORE ROAD, SUITE 100 PALO ALTO, CA 94303				
EXAMINER				
HAND, MELANIE JO				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/612,109

Applicant(s)

EWERS ET AL.

Examiner

MELANIE J. HAND

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-10, 12, 46-56 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 8-10, 12, 46-56 and 58-60 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 22, 2008 has been entered.

Response to Arguments

2. Applicant's arguments, see Remarks, filed February 22, 2008, with respect to the rejection(s) of claim(s) 1-5, 8-10, 12, 46-56 and 58-60 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

3. It is noted that independent claims 1, 46, 55, 59 and 60 as amended recite a coil that is translatably disposed within a lumen in the claimed tube. Upon further review of the claims, a further election requirement between a species of delivery catheter having a coil screw stabilization device fixedly attached to the tube and a species of delivery catheter having a coil screw stabilization device translatably disposed within the same tube should have been made. However, claim 11, which previously recited this limitation but has since been cancelled, was examined on its merits in a previous Office action. Therefore, claims 1, 46, 55, 59 and 60 as amended will be examined on their merits herein.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3-5, 8-10, 12, 46, 48-53, 55, 56 and 58-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Ewers et al (U.S. Patent Application Publication No. 2005/0245945)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With respect to **claim 1**: Ewers teaches a delivery catheter 950 for a gastric reduction system, the delivery catheter 950 comprising: an elongate torqueable and flexible tube in the form of tubular mesh 980 having a back end and a front end, a needle in the form of inner tube 960 having a sharpened distal tip as in tip 925 of the embodiment of Fig. 33 that is coaxial with and translatably disposed within the tube 980 inasmuch as Ewers teaches that the tissue grabbing assembly moves a certain distance relative to the distal end of the tube, such movement being limited. (§10078) The needle 920 as a penetrating tip to pierce the tissue wall to create contact

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points for an anchor to be inserted later. (¶¶0084,0085) At least one anchor is translatable disposed within the needle and moveable out of the penetrating tip of the needle. (¶0087) A coil 924 is present on a front end of a shaft of tube 910 that is translatable disposed as part of tissue grabbing assembly 922 within a lumen in said tube 980 via its attachment to tube 960. As a part of tissue grabbing assembly 922 that is extendible out of the front end of tube 980 to engage the tissue wall, said coil 924 is also extendible out of the front end of the tube 980.

With respect to **claim 3**: The tube contains a plurality of slots at bendable sections 25,26 of flexible tubes 13,14,respectively disposed substantially perpendicular to a longitudinal axis of the tube. (Fig. 1B, ¶0079)

With respect to **claim 4**: The slots are formed in a sinusoidal pattern. (Fig. 1B, ¶0079)

With respect to **claim 5**: As can be seen in Fig. 1B, the slot density is increased from zero near a distal end of the tube 11.

With respect to **claim 8**: The coil 18 is a coil screw and thus includes a sharpened distal tip to facilitate tissue penetration. (¶0022)

With respect to **claim 9**: The coil screw 18 necessarily comprises a plurality of coils that form a central opening for the passage of the needle 34.

With respect to **claim 10**: The coil 18 and needle 920 are substantially coaxial. (Fig. 33A)

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With respect to **claim 12**: The catheter further comprises a push rod 42 translatablely disposed within the needle 34 and adapted to push distal rod 38a out of a distal end of the needle 34, which in turn pushes the anchor out of a distal end of the needle 34. (¶¶0089,0090)

With respect to **claim 46**: Ewers teaches a catheter comprising a flexible tube 14 having a front end and a back end and a needle 34 within the tube and having a tip 24 extendible out of the front end of the tube 14. At least one anchor 36 is positioned within the flexible tube 14 and is moveable out of the flexible tube during a surgical procedure. (¶0087) A suture is connected to one or more of the anchors 36 by threading the suture through openings in the anchor 36, with the suture extending within the tube towards the back end of the tube. (Fig. 4B) A coil screw defining tissue grabbing assembly 18 is present on a front end of a shaft that is translatablely disposed within a lumen in said tube 14, said coil being extendible out of the front end of the tube. (¶¶0022,0078)

With respect to **claim 48**: The tube 11 has through slots in the bendable sections 25,26 of flexible tubes 13,14. With regard to the limitation "to increase the flexibility of the tube", the limitation constitutes functional language that is given little patentable weight herein. Further, since the prior art of Ewers anticipates the slots, the slots are fully capable of increasing the flexibility of the instant tube.

With respect to **claim 49**: The coil is a coil screw and thus has a sharp tip. (¶0022)

With respect to **claim 50**: The needle 34 has a penetrating tip in the form of distal tip 24 adjacent to the front end of the flexible tube 14. (¶0078)

With respect to **claim 51**: The needle 34 is positioned to extend out of the front end of the flexible tube 14 and through the coil 18.

With respect to **claim 52**: The catheter 11 further comprises a push rod 42, longitudinally moveable within the needle 34 for pushing one or more anchors 36 out of the tip 24 of the needle 34. (¶¶0089,0090)

With respect to **claim 53**: The needle 920 has a closed distal tip that is considered herein to be a non-coring tip inasmuch as Ewers does not disclose collection and storage of tissue within the needle.

With respect to **claim 55**: Ewers teaches a catheter comprising a bendable (i.e. flexible) and torqueable tube 11 having a front end and a back end and a needle 34 within the tube and having a piercing tip in the form of distal tip 24 extendible out of the front end of the tube. One or more anchors 36 are stored within the tube 11 and moveable out of the tube 11 for placement during a surgical procedure. (Fig. 4, ¶¶0084) A suture is connected to the anchor 36 by threading the suture through openings in the anchor 36 and leads out towards the back end of the tube 11. (Fig. 4) A coil defining tissue grabbing assembly 18 is present on a front end of a shaft that is translatably disposed within a lumen in said tube. The coil is extendible out of the front end of the tube.

With respect to **claim 56**: The tube 11 has through slots in the bendable sections 25,26 of flexible tubes 13,14. With regard to the limitation "to increase the flexibility of the tube", the

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limitation constitutes functional language that is given little patentable weight herein. Further, since the prior art of Ewers anticipates the slots, the slots are fully capable of increasing the flexibility of the instant tube.

With respect to **claim 58**: The catheter further comprises a push rod 42 longitudinally moveable within the needle 34 for pushing a distal rod 38a out of a distal end of the needle 34, which in turn pushes the anchor 36 out of a distal end of the needle 34. (Fig. 4, ¶¶0089,0090)

With respect to **claim 59**: Ewers teaches a catheter comprising a bendable (i.e. flexible) and torqueable tube 11 having a front end and a back end; a handle 16 attached adjacent to the back end of the tube. A hollow needle 34 is present within the tube and has a piercing tip 24 extendible out of the front end of the tube 11. One or more anchors 36 are present within the needle, with the anchor 36 moveable out of the piercing tip 24 of the needle via a force applied by distal rod 38a from pushing rod 42. (Fig. 4, ¶¶0089,0090) An anchor ejector in the form of pushing rod 42 is present within the needle 34. A suture is connected to the anchor by threading the suture through openings in the anchor 36 and leads out towards the handle 16. A needle control on the handle 16 in the form of a control actuator is linked to the needle 260 via needle pushrod 270 for moving the needle within the tube. An anchor ejector control is linked to the anchor ejector, namely anchor pushrod 280. A coil defining tissue grabbing assembly 18 on a front end of a shaft is translatablely disposed within a lumen in said tube 11, said coil 18 being extendible out of the front end of the tube. (¶0084)

With respect to **claim 60**: Ewers teaches a catheter comprising a flexible tube 14 having a front end and a back end, a needle 34 within the tube 14 and having a tip 24 extendible out of the

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front end of the tube 14. At least one anchor 36 is positioned within the needle and is moveable out of the needle tip 24 during a surgical procedure via force applied by pushrod 42 to distal rod 38a. A suture is connected to the anchor by threading the suture through openings in the anchor 36 and leads out towards the back end of the tube 14. A coil defining tissue grabbing assembly 18 on a front end of a shaft is translatable disposed within a lumen in said tube 11, said coil 18 being extendible out of the front end of the tube. (§0084)

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewers et al ('945).

With respect to **claim 2**: Ewers teaches a braided mesh in another embodiment of the catheter but does not disclose a braid in the embodiment of Fig. 1B. However, since the embodiment of Fig. 34B wherein the braid is disclosed in a structurally substantially identical catheter, it would

be obvious to one of ordinary skill in the art to modify the tube of the embodiment of Fig. 1B so as to be formed of a braided wire with a reasonable expectation of success. (¶0227)

With respect to **claim 47**: The tube 14 is torqueable inasmuch as it is bendable and able to be rotated by application of force by the user. Ewers does not teach that the tube 14 is formed of braided wire. However Ewers teaches an embodiment in Fig. 34B of a substantially identical catheter but with a different structural stabilization arrangement for creating the tissue fold for gastric reduction in which a tube of braided mesh formed of braided wire is disposed around the needle. Therefore it would be obvious to one of ordinary skill in the art to modify the device of Ewers such that the tube is formed of braided wire with a reasonable expectation of success.

8. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ewers et al ('945) in view of Iwami et al (U.S. Patent Application Publication No. 2002/0087098).

With respect to **claim 54**: Ewers does not teach that the tube has a coating of fluorine resins. Iwami teaches coating a catheter with fluorine resin to act as a location marker for observation of the progress of the tube during endoscopy while the tube is in the body. Since Ewers teaches that the instant apparatus is used in gastrointestinal endoscopy, it would be obvious to one of ordinary skill in the art to modify the device of Ewers such that the instant tube has a coating of fluorine resin as taught by Iwami to provide a mark on the tube to allow observation of the tube's progress during an endoscopy procedure with otherwise limited visibility. ('098, ¶¶0026,0034,0035,0102)

9. Claims 1, 9, 10, 12, 46, 51-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al (U.S. Patent Application Publication No. 2003/0167071) in view of Hayhurst (U.S. Patent No. 6,656,182).

With respect to **claim 1**: Martin teaches a delivery catheter in the form of a catheter loading tool 200 for a gastric reduction system, the delivery catheter 200 comprising an elongate tube considered herein to be torqueable inasmuch as it can be rotated or bent by application of a force from the user, and flexible inasmuch as Martin teaches that the catheter is advanced through the vascular system which defines a nonlinear path, thus necessitating a flexible catheter. Delivery catheter 200 has a back end and a front end. Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin teaches that the catheter/loading tool 200 is present in a kit along with a needle but does not teach that the needle is translatably disposed within the tube 200. Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of

Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations "needle is translatably disposed within the tube" and "at least one anchor translatably disposed within the needle, and moveable out of the penetrating tip of the needle" obvious.

With respect to **claim 9**: The coil taught by Martin comprises a plurality of coils that form a central opening for the passage of the needle of the combined teaching of Martin and Hayhurst. The motivation to modify the device of Martin so as to include a needle is stated *supra* with respect to claim 1.

With respect to **claim 10**: The coil and needle of the combined teaching of Martin and Hayhurst are substantially coaxial inasmuch as they are both disposed within the tube and thus are concentric with the instant tube. The motivation to modify the device of Martin so as to include a needle is stated *supra* with respect to claim 1.

With respect to **claim 12**: The delivery catheter 520 of Martin further comprises a push rod 522. However the rod is not translatably disposed within a needle or adapted to push the anchor out of a distal end of the needle. Hayhurst teaches that the instant needle comprises a push rod in the form of hollow needle 16 translatably disposed within the needle and adapted to push the anchor 10 out of a distal end 26 of the needle 14. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the instant delivery catheter comprises a push rod translatably disposed within a needle as taught by Hayhurst with a reasonable expectation of success.

With respect to **claim 46**: Martin teaches a catheter 200 comprising a flexible tube having a front end and a back end. Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin teaches that the catheter/loading tool 200 is present in a kit along with a needle but does not teach that the needle is translatably disposed within the tube 200. Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations "needle is translatably disposed within the tube" and "at least one anchor translatably disposed within the needle, and moveable out of the penetrating tip of the needle" obvious.

The combined teaching of Martin and Hayhurst discloses a suture connected to one or more of the anchors, with the suture extending within the tube by extending within the needle which is within the tube, towards the back end of the tube.

With respect to **claim 51**: The needle of the combined teaching of Martin and Hayhurst is positioned to extend out of the front end of the instant flexible tube and through the coil, as the coil is also disposed within the tube and defines an central opening for the needle. The motivation to modify the device of Martin so as to comprise a needle that is translatably disposed within the instant tube is stated *supra* with respect to claim 49.

With respect to **claim 52**: The delivery catheter 520 of Martin further comprises a push rod 522. However the rod is not translatably disposed within a needle or adapted to push the anchor out of a distal end of the needle. Hayhurst teaches that the instant needle comprises a push rod in the form of hollow needle 16 translatably disposed within the needle and adapted to push the anchor 10 out of a distal end 26 of the needle 14. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the instant delivery catheter comprises a push rod translatably disposed within a needle as taught by Hayhurst with a reasonable expectation of success.

With respect to **claim 53**: The needle of the combined teaching of Martin and Hayhurst is considered herein to have a noncoring tip 26 inasmuch as the lumen of the tip either contains an anchor or push rod at any given time and thus is not functional to core the tissue.

With respect to **claim 55**: Martin teaches a catheter 200 comprising a flexible and torqueable tube having a front end and a back end. Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in

said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin teaches that the catheter/loading tool 200 is present in a kit along with a needle but does not teach that the needle is translatably disposed within the tube 200. Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations "needle is translatably disposed within the tube" and "at least one anchor translatably disposed within the needle, and moveable out of the penetrating tip of the needle" obvious.

The combined teaching of Martin and Hayhurst discloses a suture connected to one or more of the anchors, with the suture extending within the tube by extending within the needle which is within the tube, towards the back end of the tube.

With respect to **claim 58**: The delivery catheter 520 of Martin further comprises a push rod 522. However the rod is not translatably disposed within a needle or adapted to push the anchor out of a distal end of the needle. Hayhurst teaches that the instant needle comprises a push rod in

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the form of hollow needle 16 translatably disposed within the needle and adapted to push the anchor 10 out of a distal end 26 of the needle 14. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the instant delivery catheter comprises a push rod translatably disposed within a needle as taught by Hayhurst with a reasonable expectation of success.

With respect to **claim 59**: Martin teaches a catheter 200 comprising a flexible and torqueable tube having a front end and a back end and a handle attached adjacent to the back end of the tube, since catheter 200 is a loading tool that is advanced through the vascular system manually by a caregiver. ('071, 0058) Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin does not disclose the presence of a hollow needle within the tube having a piercing tip extendible out of the front end of the tube. Hayhurst teaches a tissue fastening device comprising a hollow needle 14 having a piercing tip 26 extending out of the front end of the device. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating

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tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations "needle is translatably disposed within the tube" and "at least one anchor translatably disposed within the needle, and moveable out of the piercing tip of the needle" obvious.

Hayhurst teaches an anchor ejector in the form of a push rod 16 within the needle 14. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the instant delivery catheter comprises a push rod translatably disposed within a needle as taught by Hayhurst with a reasonable expectation of success.

Martin does not teach a needle control on the handle linked to the needle for moving the needle within the tube. However since the combined teaching of Martin and Hayhurst teaches a needle within the tube that is responsible for piercing or fastening tissue areas together, it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Martin and Hayhurst so as to include a needle control on the handle linked to the needle to provide a means for controlling the movement and piercing action of the needle to the operator.

The combined teaching of Martin and Hayhurst discloses that the control of the anchor ejector lies in the pushing motion applied by the user at will. An anchor ejector control on the handle linked to the anchor ejector would simply be another, automated means of accomplishing the instantly disclosed manually completed task of controlling the motion of the anchor ejector. Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Martin and Hayhurst so as to include an anchor ejector control on the handle linked to the anchor ejector, hollow needle/push rod 16, to provide an

alternate automated means for controlling the motion of the needle/push rod, thus controlling the ejection of the anchors until they are needed.

The combined teaching of Martin and Hayhurst discloses a suture connected to one or more of the anchors, with the suture extending within the tube by extending within the needle which is within the tube, toward the handle.

With respect to **claim 60**: Martin teaches a catheter 200 comprising a flexible tube having a front end and a back end. Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin teaches that the catheter/loading tool 200 is present in a kit along with a needle but does not teach that the needle is translatably disposed within the tube 200. Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations "needle is translatably disposed within the tube" and "at least

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one anchor translatable disposed within the needle, and moveable out of the penetrating tip of the needle" obvious.

The combined teaching of Martin and Hayhurst discloses a suture connected to one or more of the anchors, with the suture extending within the tube by extending within the needle which is within the tube, towards the back end of the tube.

10. Claims 2, 3, 5, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of Hayhurst ('182) as applied to claim 1 above, and further in view of Madrid et al (U.S. Patent Application Publication No. 2002/058905).

With respect to **claim 2**: Martin does not teach that the tube is formed of braided wire. Hayhurst teaches that the anchor member is formed of braided wire material but also does not teach a tube that the needle and anchor are disposed within a tube formed of braided wire as recited in claim 2. Madrid teaches that catheters formed of braided stainless steel are well known in the art, therefore it would be obvious to one of ordinary skill in the art to modify the device of Martin and Hayhurst such that the tube is formed of braided stainless steel with a reasonable expectation of success. ('905, 0046) Thus, the combined teaching of Martin and Hayhurst and Madrid renders the limitation "wherein the tube is formed of braided wire" obvious.

With respect to **claim 3**: The tube of the combined teaching of Martin and Hayhurst and Madrid is formed of braided wire and thus necessarily contains a plurality of slots disposed substantially perpendicular to a longitudinal axis of the tube. The motivation to modify the combined teaching of Martin and Hayhurst such that the instant tube is formed of braided wire is stated *supra* with respect to claim 2.

With respect to **claim 5**: The slot density of the combined teaching of Martin and Hayhurst and Madrid is increased near a distal end of the tube due to the presence of the braiding material when compared to the tube without the braided material. The motivation to modify the combined teaching of Martin and Hayhurst such that the instant tube is formed of braided wire is stated *supra* with respect to claim 2.

With respect to **claim 47**: The tube of catheter 200 of Martin is torqueable. Martin does not teach that the tube is formed of braided wire. Hayhurst teaches that the anchor member is formed of braided wire material but also does not teach a tube that the needle and anchor are disposed within a tube formed of braided wire as recited in claim 2. Madrid teaches that catheters formed of braided stainless steel are well known in the art. Therefore it would be obvious to one of ordinary skill in the art to modify the device of Martin and Hayhurst such that the tube is formed of braided stainless steel with a reasonable expectation of success. ('905, 0046) Thus, the combined teaching of Martin and Hayhurst and Madrid renders the limitation "wherein the tube is formed of braided wire" obvious.

With respect to **claim 48**: The tube of the combined teaching of Martin and Hayhurst and Madrid is formed of braided wire and thus necessarily contains a plurality of slots disposed substantially perpendicular to a longitudinal axis of the tube. The motivation to modify the combined teaching of Martin and Hayhurst such that the instant tube is formed of braided wire is stated *supra* with respect to claim 47.

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11. Claims 8 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of Hayhurst ('182) as applied to claim 1 above, and further in view of Kortenbach (U.S. Patent Application Publication No. 2003/0208211).

With respect to **claim 8**: Martin does not explicitly teach that the coil includes a sharpened distal tip. Hayhurst also does not teach a coil having a sharpened distal tip. Kortenbach teaches a coil tissue fastening device substantially identical in structure to the coil fastening element taught by Martin. As can be seen in any of the figures disclosed by Kortenbach the coil includes a sharpened distal tip. Kortenbach refers to this as a screw arrangement to facilitate tissue penetration for fastening the tissues together and teaches that such arrangement is known in the art. ('211, 0041) Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Martin and Hayhurst such that the instant coil includes a sharpened distal tip as taught by Kortenbach with a reasonable expectation of success to ensure that the tissues are securely fastened together.

With respect to **claim 49**: Martin does not explicitly teach that the coil includes a sharp tip. Hayhurst also does not teach a coil having a sharpened distal tip. Kortenbach teaches a coil tissue fastening device substantially identical in structure to the coil fastening element taught by Martin. As can be seen in any of the figures disclosed by Kortenbach the coil includes a sharpened distal tip. Kortenbach refers to this as a screw arrangement to facilitate tissue penetration for fastening the tissues together and teaches that such arrangement is known in the art. ('211, 0041) Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Martin and Hayhurst such that the instant coil includes a

sharp tip as taught by Kortenbach with a reasonable expectation of success to ensure that the tissues are securely fastened together.

The combined teaching of Martin and Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26 adjacent to the front end of the instant tube, namely the end closest to the tissue. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin so as to comprise a needle 14 having a penetrating tip 26 adjacent to the front end of the instant tube with a reasonable expectation of success to more easily penetrate adjacent tissue.

12. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of Hayhurst ('182) as applied to claim 46 above, and further in view of Iwami et al (U.S. Patent Application Publication No. 2002/0087098).

With respect to **claim 54**: The combined teaching of Martin and Hayhurst does not disclose a tube having a coating of fluorine resin. Iwami teaches coating a catheter with fluorine resin to act as a location marker for observation of the progress of the tube during endoscopy while the tube is in the body. Since Ewers teaches that the instant apparatus is used in gastrointestinal endoscopy, it would be obvious to one of ordinary skill in the art to modify the device of Martin such that the instant tube has a coating of fluorine resin as taught by Iwami to provide a mark on the tube to allow observation of the tube's progress during an endoscopy procedure with otherwise limited visibility. ('098, ¶¶0026,0034,0035,0102)

13. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of Hayhurst ('182) as applied to claim 46 above, and further in view of O'Keefe (U.S. Patent No. 6,921,378).

With respect to **claim 56**: The combined teaching of Martin and Hayhurst does not disclose a tube having through slots. O'Keefe teaches a drainage catheter having a plurality of slots extending substantially perpendicular to a longitudinal axis of the tube and present only at a distal end of a catheter, therefore increasing in density as the length from the distal end decreases, and that these slots are of a curved shape. O'Keefe teaches that these slots are used to aid liquid flow through the retention end of the catheter. ('378, Col. 11, lines 4-11) Therefore placing slots in delivery catheter 520 at a distal end would be obvious to one of ordinary skill in the art as the catheter 520 performs a substantially identical function to that taught by O'Keefe.

With regard to the limitation "to increase the flexibility of the tube", such limitation constitutes functional language that is given little patentable weight herein. Since the combined teaching of Martin and Hayhurst and O'Keefe renders the limitation of claim 56 as to a tube having through holes, the combined teaching of Martin and Hayhurst and O'Keefe also renders the limitation "to increase the flexibility of the tube" obvious.

Allowable Subject Matter

14. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

15. The following is a statement of reasons for the indication of allowable subject matter: A thorough search of the prior art of record did not disclose any reference, alone or in combination with other reference(s) that teaches or fairly suggests a catheter comprising a tube having slots therethrough formed in a sinusoidal pattern. The closest prior art of record is the combined teaching of Martin and Hayhurst and Madrid. The combined teaching discloses the invention substantially as claimed except for holes formed in a sinusoidal pattern. The holes of the instant tube are formed by the braided wire and are thus quadrilateral in nature. Modification of the holes to be formed in a sinusoidal pattern would require destruction of the braid and thus destruction of the tube, which would in turn destroy the function of the device of Martin. Thus, such a modification is not taught or fairly suggested by the closest prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Melanie J Hand/
Examiner, Art Unit 3761